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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,034	12/04/2000	Cheryl A. Pederson	56094USA1A.002	4710
32692 7590 04/05/2007 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			EXAMINER KOPPIKAR, VIVEK D	
			ART UNIT 3626	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/05/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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<b>Office Action Summary</b>	<b>Application No.</b> 09/729,034	<b>Applicant(s)</b> PEDERSON ET AL.	
	<b>Examiner</b> Vivek D. Koppikar	<b>Art Unit</b> 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Application*

1. Claims 12-33 have been examined in this application. This communication is a Final Office Action in response to the "Amendment" and "Remarks" filed on January 23, 2007.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 12-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al., 'Guideline for prevention of surgical site infection' (hereinafter Guidelines) in view of Ormond-Walshe, Sarah, "Computerized databases in infection control" (hereinafter Walshe) and in further view of US Patent Number 6,157,853 to Blume and in even further view of US Patent Number 5,562,448 to Mushabac.

(A) As per claim 12-13, Guidelines discloses a method for managing the occurrence or risk of surgical site infection incident to a surgical procedure (Guidelines: pages 100-120), the method comprising:

(a) identifies a plurality of stages (mapping) of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage, and a postoperative stage (Guidelines: page 98);

(b) identifies one or more points-of-care within each identified stage of operative care associated with the surgical procedure (Guidelines: page 98);

Art Unit: 3626

(c) for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated with a surgical procedure sources of measurable risk of surgical site infection (Guidelines: page 98);

(d) for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk (Guidelines: pages 106-116)

Guidelines do not explicitly disclose that the identified practice or practices associated with the surgical procedure within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care (pages 100-120)

Guidelines does not explicitly disclose

Aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection. However, Walshe discloses aligning the practices in a manner that provides a desired management (monitoring) of the overall occurrence or risk of surgical site infection (i.e. establishment of surveillance and control programs was strongly associated with reductions ...)(page 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of reducing infection rates (page 3).

Guidelines and Walshe does not explicitly disclose that for each of the compliance indicators, generating a flag when a given health care practice is not in compliance with a rule to align the health care practices to the rule, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

(B) As per claims 14-21, these claims are substantially similar in scope to claims 12-13 and are rejected on the same basis. The limitations claimed in these claims are taught in Guidelines(Pages 100-120).

(C) As per claim 22, Guidelines discloses a method for managing risks for surgical site infections incident to a surgical procedure, the method comprising:

evaluating a practice associated with the surgical procedure that poses an infection risk during a stage or the surgical procedure (Guidelines: Page 106-116);

Guidelines does not disclose storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedures, however, this feature is taught by Walshe (Walshe: Page 3, Paragraph 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the

Art Unit: 3626

aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of developing an enhanced means of reducing infection rates (page 3).

Guidelines in view of Walshe does not teach a step of identifying when the data indicative of the practice associated with a procedure is not in compliance with a rule established for the practice, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

(D) As per claim 23, in the combined method of Guidelines in view of Walshe and Jacober the step of identifying when the data indicative of the practice is not in compliance with the rule comprises generating a flag for the data (Jacoer: Claims 32 and 35). The motivation for making this modification to the method of guidelines is the same as set forth above in the rejection of claim 22.

Art Unit: 3626

(E) As per claims 24-25, in the combined method of Guidelines in view of Walshe and Jacober further comprises a step of prompting medical personnel to take further action when the flag is generated (Jacoher: Claims 32-35) and the flag is cleared when the further action is taken (Jacoher: Claim 34). The motivation for making this modification to the method of guidelines is the same as set forth above in the rejection of claim 22. (Note: In Jacober the medical personnel takes further action by sliding the tray of the medication dispenser to remove the medication (Claim 32)).

(F) As per claims 26-33, these claims repeat features previously addressed in the rejection of claims 12-25 and are rejected on the same basis.

#### ***Response to Arguments***

4. Applicant's arguments filed on January 23, 2007 in the "Remarks" section have been fully considered but they are not persuasive. The applicants arguments will be addressed in sequential order as they were recited in "Remarks" section.

(1) Applicants argue that in the Mushabac reference an alert is generated when a deal tool is mis-positioned which is nothing akin to the features of the Applicants' claims, e.g. generating a flag when a given health care practice is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure. Applicants go on to argue that the alert in Mushabac relates to dental tool mis-alignment and therefore has no relevance to the management of risks of surgical site infection incident to the surgical procedure.

To respond to this argument, the Examiner would like to point out that aligning a tool in a standard manner can be considered a health care practice (i.e. uniform standard for conducting a

Art Unit: 3626

health care procedure) because the Mushabac references relates to dental surgery and dental care is a type of health care.

(2) Applicants argue that the Mushabac nor the Bloom reference have any relevance to the management of surgical site infection incident to the surgical procedure, however, this teachings is disclosed by the Ormond-Walshe reference and proper motivation is given to combine all the references used in the rejection of the claims.

### ***Examiner's Suggestions***

5. The Examiner recommends filing a Request For Continued Examination (RCE) and amending the claims to more specifically delineate and identify what exactly the given health care practices associated with the surgical procedure (practices that reduce the risk of the occurrence of surgical site infection) entail, in order to overcome the prior art of record. The claims, as currently written, include the term "health care practice" which is a very broad term.

In addition, the applicants are encouraged to claim a specific formula or mathematical relation for the step of "identifying when the data indicative of any of the practices is not in compliance with a rule established for the given practice." Particularly what type of data is used to determine that an ongoing surgical procedure is not in compliance with a given health care practice.

Applicants are advised that any amendment to the claims must have support in the specification as originally filed and any amendment will be subject to an updated prior art search.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



Art Unit: 3626

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/729,034

Page 9

Art Unit: 3626

Sincerely, *VKD*

Vivek Koppikar

3/28/2007

*THOMAS A. DIXON*  
THOMAS A. DIXON  
PRIMARY EXAMINER